K002699

FEB 1 5 2001

510(k) Summary
for
PARIETEX® COMPOSITE Mesh

1. SPONSOR

Sofradim Production
116 Avenue du Formans
01600 Trevoux
France

Contact: Patrice Becker
Telephone: 33 (0)4 74 08 90 00
Facsimile: 33 (0)4 74 08 90 02

2. DEVICE NAME

Proprietary Name: PARIETEX® COMPOSITE Mesh
Common/Usual Name: Surgical Mesh
Classification Name: Surgical Mesh

3. PREDICATE DEVICES

Sofradim Parietex® Meshes, K982532
Bard Composix Mesh, K971745
Genzyme Corporation Sepramesh Biosurgical Composite Mesh, K994328
Tissue Science Laboratories, PLC Permacol, K992556

4. DEVICE DESCRIPTION

The PARIETEX® COMPOSITE Mesh is a surgical mesh used during open (laparotomy) procedures or during laparoscopic procedures. The PARIETEX® COMPOSITE Mesh is made from polyethylene terephtalate (polyester) and a collagen based hydrogel component. The hydrophilic collagen film does not affect the physical performance characteristics of the mesh but serves to separate the coated side of the mesh from underlying tissues to minimize tissue attachment and ingrowth.

The PARIETEX® COMPOSITE Mesh is offered in several sizes and shapes to accommodate the type and approach of the operation.

5. INTENDED USE

The Parietex Composite Mesh is used for the reinforcement of tissues during surgical repair. It is indicated for the treatment of incisional hernias, abdominal wall repair, parietal (i.e., pertaining to the walls) reinforcement of tissues. The non-resorbable three-dimensional mesh provides long-term reinforcement of soft tissues. On the opposite side, the resorbable hydrophilic film minimizes tissue attachment to the mesh in case of direct contact with the viscera.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Sofradim PARIETEX® COMPOSITE Mesh is composed of two biocompatible components: polyester mesh and a hydrophilic collagen film. The polyester mesh used in the Sofradim PARIETEX® COMPOSITE mesh is identical to the polyester mesh used in the Sofradim PARIETEX® Mesh (K982532). The collagen component of the Sofradim mesh is derived from a US source and meets all the requirements in the FDA collagen guidance documents. In addition, the Sofradim mesh and predicate devices are available in various sizes and shapes to accommodate different surgical procedures.

7. PERFORMANCE TESTING

Biocompatibility testing demonstrates that the materials used in the Sofradim PCO mesh are biocompatible and safe for its intended use.

Testing was performed to determine the performance characteristics of the Mesh. The density, thickness, elongation, breaking strength, tear resistance, burst resistance, and tensile strength were all evaluated. The test results showed that the Sofradim PARIETEX® COMPOSITE Mesh has similar performance characteristics as previously cleared surgical meshes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Mary McNamara-Cullinane, RAC
Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K002699
Trade Name: Sofradim PARIETEX®
Regulatory Class: II
Product Code: FTL
Dated: November 22, 2000
Received: November 24, 2000

Dear Ms. McNamara-Cullinane:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K002699

510(k) Number (if known):

Device Name: Sofradim PARIETEX®COMPOSITE (PCO) Mesh

Indications For Use:

The Parietex Composite Mesh (PCO) is used for the reinforcement of tissues during surgical repair. It is indicated for the treatment of incisional hernias, abdominal wall repair, parietal (i.e., pertaining to the walls) reinforcement of tissues. The non-resorbable three-dimensional polyester mesh provides long-term reinforcement of soft tissues. On the opposite side, the resorbable hydrophilic film minimizes tissue attachment to the mesh in case of direct contact with the viscera.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K002699

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109